DENKA SEIKEN CO.,LTD.
3-4-2, Nihonbashi kayabacho, Chuo-ku, Tokyo, Japan 103-0025

JUN - 2 2003

I. 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510 (k) number is: K030546

(A) (1) Submitter's name: Denka Seiken Co., Ltd.

Submitter's address: 3-4-2, Nihonbashi kayabacho,
Chuo-ku
Tokyo, Japan 103-0025

Submitter's telephone number: (03) 3669-9421

Contact Person: Mr. Toshimi Matsunaga
Manager
Regulatory & Pharmaceutical Affairs

Date Summary Prepared: February 17, 2003

(2) Trade or proprietary device name: CRP(II) Calibrators
Common or usual name: Calibrators for latex-enhanced turbidimetric in vitro immunoassay for determination of C-Reactive Protein
Panel: Immunology
Class: II

(3) Device intended use:

The CRP(II) Calibrator is intended to be used for the calibration of the CRP-Latex(II)X2 SEIKEN

(4) Performance data:

The CRP-Latex (II) "Seiken"X2 High Sensitivity Assay and the predicate device, N High Sensitivity CRP Assay have only minor difference that do not affect the performance, safety or effectiveness of the measurement.

The lower level of detection (sensitivity of the assay) is at 0.05mg/L, with the assay range up to 10.0 mg/L.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Toshimi Matsunaga
Manager Regulatory & Pharmaceutical Affairs
Denka Seiken Co., Limited
1-2-2 Minamihoncho, Gosen City
Niigata, Japan 959-1695

JUN - 2 2003

Re: k030546
Trade/Device Name: CRP (II) Calibrators
Regulation Number: 21 CFR § 862.1150
Regulation Name: Calibrator Primary
Regulatory Class: II
Product Code: JIS
Dated: April 30, 2003
Received: May 5, 2003

Dear Mr. Matsunaga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

C. Indications for use of the Calibrator

510(k) Number): K030546

Device Name: CRP (II) Calibrators

Indications for Use:

The CRP(II) Calibrators are intended to be used for the calibration of the CRP-Latex (II)X2 SEIKEN Assay kit for quantitating CRP (C-reactive protein) in human serum and EDTA or lithium heparinized plasma samples.

(Please do not write below this line—continue on another page if needed)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_X___or Over-the-Counter Use _____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

JRaws for J. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K030546